IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC. AND CYTYC SURGICAL PRODUCTS, LLC,	)	
Plaintiffs,	)	
v.	)	Civ. No. 15-1031-SLR
MINERVA SURGICAL, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 1st day of June, 2016, having reviewed the papers filed in connection with Minerva's motion for preliminary injunction, and having heard oral argument on same;

IT IS ORDERED that Minerva's motion (D.I. 94) is denied, for the reasons that follow:

1. **Procedural background.**[1] On November 6, 2015, plaintiffs Hologic, Inc. and Cytyc Surgical Products, LLC ("Cytyc"), (collectively "Hologic"), filed a complaint alleging infringement of U.S. Patent Nos. 6,872,183, 8,998,898, and 9,095,348 ("the '348 patent"), against defendant Minerva Surgical Inc. ("Minerva").[2] (D.I. 1) On February 5, 2016, Hologic filed a second amended complaint pursuant to a stipulation, adding allegations relating to U.S. Patent No. 9,247,989. (D.I. 69, 70) On February 29, 2016,

[1] The court presents only the background needed for the dispute at bar. A fuller recitation of the background of the present litigation is presented in the order on Hologic's motion for preliminary injunction.

[2] On January 6, 2016, Minerva filed a motion to dismiss, which was subsequently withdrawn. (D.I. 43, 62) On January 25, 2016, Hologic filed an amended complaint. (D.I. 59)

the court denied Minerva's motion to transfer and strike Hologic's preliminary injunction motion.[3] (D.I. 82) On March 4, 2016, Minerva answered the complaint and counterclaimed for, inter alia, unfair competition under the Lanham Act, Title 15 of the United States Code § 1125(a) & (c); deceptive trade practices under Title 6 of the Delaware Code § 2532; unfair competition under Delaware common law; and trade libel. (D.I. 83) On March 28, 2016, Hologic answered the counterclaims. (D.I. 106)

2. **Factual background.** "Menorrhagia" is abnormally heavy menstrual bleeding in amount or duration. NovaCept Corporation ("NovaCept")[4] under the direction of Csaba Truckai ("Truckai") and his design team, developed the NovaSure system ("NovaSure") in the late-1990s for the treatment of menorrhagia. The U.S. Food and Drug Administration ("FDA") approved NovaSure in 2001. (D.I. 70 at ¶ 10; D.I. 86 at 2) In July 2015, Minerva also obtained FDA approval for a new device for the treatment of menorrhagia ("Minerva EAS"), developed by Truckai and his design team. Minerva has hired and trained a sales force to begin selling Minerva EAS to physicians. (D.I. 86 at 4)

3. In the late 1990s, NovaCept created two videos showing ablation of a liver using a prototype NovaSure device – in one video, suction is applied to the cavity in the liver, in the other no suction is applied. (D.I. 93, exs. 8-9) The "without suction" video depicts the formation of a "steam pocket" and the resulting uneven ablation. Since 2001, Hologic's sales associates have used the videos to show the importance of removing hot fluid from the uterus during a NovaSure ablation using NovaSure's moisture transport feature. (D.I. 107 at 2; D.I. 109, ex. 5 at 97:22-98:20, 109:20-110:2)

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[3] The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).
[4] In May 2004, Cytyc Corporation acquired NovaCept for $325 million and in 2007, Hologic Inc. acquired Cytyc Corporation. (D.I. 11 at 5; D.I. 86 at 2)

4. **Standard.** As explained by the United States Court of Appeals for the Third Circuit,

> [p]reliminary injunctive relief is an "extraordinary remedy, which should be granted only in limited circumstances." . . . "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." . . . The "failure to establish any element . . . renders a preliminary injunction inappropriate." . . . The movant bears the burden of showing that these four factors weigh in favor of granting the injunction.

Ferring Pharm., Inc. v. Watson Pharm., Inc., 765 F.3d 205, 210 (3d Cir. 2014) (citations omitted). "'[O]ne of the goals of the preliminary injunction analysis is to maintain the status quo, defined as the last, peaceable, noncontested status of the parties.'" *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). "[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and . . . such discretion must be exercised consistent with traditional principles of equity . . . ." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

5. **Likelihood of success on the merits.** Liability under the Lanham Act arises under two theories: "(1) an advertisement may be false on its face; or (2) the advertisement may be literally true, but given the merchandising context, it nevertheless is likely to mislead and confuse consumers." *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 943 (3d Cir. 1993) (citation omitted). The test for literal falsity is an objective one for the court's determination. "[I]f a defendant's claim is untrue, it must be deemed literally false" regardless of the advertisement's impact on the buying public. *Id.* at 943-44. Further, "only an unambiguous message can be literally false," and "[a] literally false message may be either explicit or conveyed by necessary implication when,

considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Novartis Consumer Health Inc. v. Johnson & Johnson–Merck Consumer Pharms. Co.*, 290 F.3d 578, 586-87 (3d Cir. 2002) (quoting *Clorox Co. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 35 (1st Cir. 2000)) (internal quotations and emphasis omitted). Conversely, "[w]hen the challenged advertisement is implicitly rather than explicitly false, its tendency to violate the Lanham Act by misleading, confusing or deceiving should be tested by public reaction." *Castrol*, 987 F.2d at 943 (citing *Coca-Cola Co. v. Tropicana Prod., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982).

6. Minerva asserts[5] by way of the declaration of its vice president of sales and marketing, Thomas Pendlebury ("Pendlebury"), that Hologic's sales representatives use the videos to "either state or suggest that the 'with suction' video portrays Nova[S]ure's 'controlled' ablation whereas the 'without suction' video portrays an 'uncontrolled' ablation including tissue that bubbles and deforms as a result of the 'uncontrolled' procedure." Moreover, Hologic's sales representatives "explain or imply that the 'without suction' video is, reflects, and/or embodies Minerva's technology and methods" or "have expressly and falsely told physicians that the 'without suction' video is Minerva's system." Pendlebury also states that Hologic's sales representatives have in some instances told physicians that the "without suction" video demonstrates the "risk" associated with the technology underlying Minerva's system. (D.I. 91 at ¶¶ 21-22)

[5] On February 16, 2016, Minerva requested that Hologic cease and desist from using the videos and requested that Hologic send a corrective letter to those who saw them. Hologic responded that it would investigate the issue. (D.I. 87, exs. 97, 98)

Minerva points to discussions from internal Hologic "talk track" meetings[6] about Minerva's entry into the market and how Hologic's sales representatives might use the videos to market NovaSure over Minerva EAS. (D.I. 87, ex. 96 at 65917-20, ex. 99 at 100971, ex. 100 at 100522, ex. 101 at 101415, ex. 102 at 100605)

7. Hologic's internal sales guidance documents instruct its representatives to not use the videos "to say this is what will happen in the absence of suction." Instead, the video without suction may be used to show "a RISK of what can happen with Minerva" EAS. (D.I. 109, ex. 6 at 136781) The '348 patent explains that "liquid build-up at the ablation site is detrimental" and that moisture is shunted away from the ablation site, preventing liquid build-up. ('348 patent, 11:1-13) Minerva's U.S. Patent No. 9,050,103 also states that "vapor . . . can collect in pockets between an exterior surface of the expanded structure and an inner wall of the uterus . . . [and] can reduce the efficiency of energy transfer into the uterine wall and is therefore undesirable." (D.I. 108, ex. 10 at 2:13-18) NovaSure actively applies a vacuum to achieve suction during ablation; Minerva EAS does not. (D.I. 107 at 2)

8. Minerva's evidence consists of the declaration of Pendlebury. As to explicit literal falsity, Pendlebury states that some physicians were told the "without suction" video represents Minerva EAS. The videos are 15 years old and depict a prototype of NovaSure, which dispels the notion that a sales representative would assert that the video is an ablation performed with Minerva EAS. The "talk track" statements contain salesmanship language such as "what you might see during a Minerva ablation" or questions such as "Minerva technology doesn't have a vacuum so why would ablating

[6] Meetings used to brainstorm sales approaches.

with steam be any safer 15 years later?" Even analyzing these statements in conjunction with the fact that NovaSure uses suction and Minerva EAS does not, such statements do not impliedly confer that the video represents Minerva EAS. *Novartis*, 290 F.3d at 587 ("The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, however, the less likely it is that a finding of literal falsity will be supported.") (citations omitted). The court turns its attention to the second theory of liability, that is whether such statements (if made) would be "likely to mislead and confuse" physicians. There is no direct evidence of confusion in the record. Indeed, Pendlebury states that he has "received a number of reports from physicians regarding conversations they have had with Hologic representatives." As the physicians are contacting Minerva to report the conversations, the physicians may not be said to be confused by the videos.

9. Minerva briefly alleges that Hologic is making misrepresentations to physicians regarding the safety of Minerva EAS, opining in a footnote that "in its [o]pposition and advertising, Hologic claims that NovaSure's rate of thermal injury is 1 in 10,000." (D.I. 113 at 3 n.3; D.I. 91 at ¶ 24) The parties reference the FDA's Manufacturer and User Facility Device Experience database, which cautions users that "MDR data alone cannot be used to establish rates of events . . . or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices."[7] Given that any data provided to physicians is taken from a public FDA database, Minerva has not established that such data is misleading or

[7] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

confusing to physicians. Without a showing of literal falsity or confusion, Minerva has not shown a likelihood of success on the merits.[8]

10. **Irreparable harm.** Pendlebury posits that Minerva has lost sales and will continue to lose sales as a result of the deceptive communications. Minerva concludes that the representations are damaging its goodwill and reputation. On the record at bar, Minerva has generally alleged lost sales, but has not established that the alleged misrepresentations are responsible for these. Moreover, should Minerva ultimately succeed on the merits of its counterclaims, money damages may compensate for any lost sales.

11. **Balance of equities.** This factor is largely neutral. Minerva alleges that stopping the use of the videos and preventing Hologic from making false and deceptive representations about Minerva EAS would have a minimal impact on Hologic. Hologic, however, has been using the videos since 2001 to illustrate the benefits of NovaSure's moisture transport feature.

12. **Public interest.** This factor is largely neutral. Minerva provides a vague allegation about Hologic's statements regarding the safety of Minerva EAS. However, the FDA has approved Minerva EAS and any analysis of its safety is outside the purview of the court in the present context. Likewise, physicians are certainly capable of drawing their own conclusions from information provided by 15-year-old videos,

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[8] Minerva relies on the same evidence and analysis to conclude that it will succeed on the merits of the additional counterclaims for deceptive trade practices under Title 6 of the Delaware Code § 2532; unfair competition under Delaware common law; and trade libel. As such, the court declines to separately analyze these counterclaims.

representations by sales representatives, and information provided on a public FDA website. The court will not substitute its judgment in this regard on the record at bar.

13. **Conclusion.** For the foregoing reasons, Minerva's motion for preliminary injunction is denied.

United States District Judge